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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,591	11/14/2003	Janakiraman Ramachandran	GANG-006	3234

24353 7590 10/18/2006

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

KINSEY, NICOLE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,591

Applicant(s)

RAMACHANDRAN ET AL.

Examiner

Nicole E. Kinsey, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/21/05, 6/14/05, 8/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group II (Claims 10-13) in the reply filed on 8/11/2006 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search on all of the claims together in the present application and that a search to identify art relevant to the composition claims of Group II would at the same time identify art relevant to the method claims of Groups I and III. This is not found persuasive because the subject matter of the different groups requires different searches that are not co-extensive. Just because each group requires a generic bacteriophage does not mean that searching the phage alone will cover every method involving phages. Further, a method for inhibiting bacterial growth is not the same as a method of making a phage. Thus, different searches will be required for each group.

Applicants' argument that the search for composition claims will identify art relevant to the method claims does not address the search burden. Applicants have submitted only conclusory statements and no specific rebuttal to the restriction requirement to demonstrate that there would be no serious burden on the Examiner. Applicant is required to submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if one of the inventions is found to be unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informalities: The address for the ATCC on page 16, line 3 should recite Virginia as the state and not Maryland.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson-Boaz et al.

Johnson-Boaz et al. describes the production and isolation of bacteriophages (Arj1) that have a mutation in their holin or S gene (i.e., holin-modified). The phages are isolated in buffer or water (see Experimental Procedures, pages 502-503). In addition, the phages cause early lysis in its host, thus inactivating the host and producing extremely low titers of phage progeny (page 497, Isolation of the early-lysis mutant).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson-Boaz et al. in view of Taylor et al. (U.S. Patent No. 2,851,006) and Clark.

The disclosure of Johnson-Boaz et al. is discussed under 35 U.S.C. 102(b). Johnson-Boaz et al. does not teach a lyophilized form of phage or a composition of two or more different holin-modified bacteriophage that effect inhibition of at least two different bacterial hosts.

Clark discloses lyophilized phage preparations that contained viable phage.

It would have been obvious to one of ordinary skill in the art to lyophilize a phage preparation for storage purposes as taught by Clark. One would have been motivated to do so, given the suggestion by Clark that lyophilization is a very convenient method for preserving phage. There would have been a reasonable expectation of success, given the fact that it is well known in the art that lyophilization is commonly used to preserve microorganisms. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

With regard to a two-phage composition, it is well known in the art that compositions containing more than one different phage, each specific for a different host, will provide broader bactericidal effects. For example, Taylor et al. teaches that cocktails of phages should be used to assure the destruction of all possible species of contaminating bacteria, namely Salmonella (col. 2, lines 25-44). Thus, it would have been obvious for one of ordinary skill in the art to combine two or more different phages

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in a composition as suggested by Taylor et al. There would have been a reasonable expectation of success given the knowledge that phages kill bacteria and also given the knowledge that more than one strain or species of bacteria can contaminate/infect an object. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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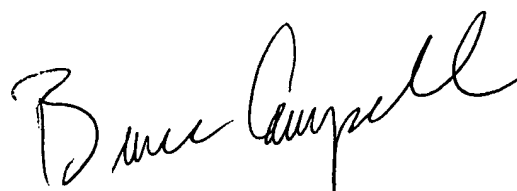
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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E Kinsey, Ph.D.

Examiner

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A handwritten signature in cursive script that reads "Bruce R. Campell".

**BRUCE R. CAMPPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**